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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,857	10/07/2008	Hans Lemernas	02314-26109.PCT.US	8109

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EXAMINER
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AL-AWADI, DANAH J

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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07/09/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/576,857

**Applicant(s)**

LENNERNAS ET AL.

**Examiner**

DANAH AL-AWADI

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 73-145 is/are pending in the application.
- 4a) Of the above claim(s) 17-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CS-100)
- Paper No(s)/Mail Date 2 pages: 07/21/2006
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Examiner thanks the Applicants for their timely reply filed on 07 April 2010.

Applicants' election **with** traverse of Group I claims 73-116 is acknowledged. The traversal is on the grounds that there are specific therapeutic agents recited in the instant application that differ to the US 2003170307 application. Furthermore, applicants state that the claims require a ruptured structure not present in the US 2003170307 application.

In response the Examiner respectfully submits, that independent claim 73 does not recite specific therapeutic agents and claims an immune system modulator as the active agent. The US 2003170307 application teaches anti-inflammatory agents which would be considered immune system modulators. With regards to the ruptured structure, the '307 publication teaches that the matrix has a porosity ([0037]). This reads on having a ruptured foam-like structure.

Claims 117-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and inventions, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Rejections- 35 USC § 112 First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 73 is a rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while being enabled for therapeutically and diagnostically active substances, does not reasonably provide enablement for prophylactically active substances. Applicant's specification is enabled for diagnostically active substances and therapeutically active substances, but is not enabled for the preventative agents.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Wands*, 8 USPQ2d 1404. Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or

guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

**(A) The nature of the invention:**

The invention is drawn to a composition comprising i) hydrating ceramics ii)expandable agents iii)a sorbed aqueous medium and iv)one or more therapeutically, prophylactically, and/or diagnostically active substances.

To prevent means to keep from occurring and the term implies that a condition will not occur, not just that the severity of the symptoms associated with the disease are reduced or that the onset of the condition is delayed.

**(B) The breadth of the claims:**

The invention is drawn to a composition comprising i) hydrating ceramics ii)expandable agents iii)a sorbed aqueous medium and iv)one or more therapeutically, prophylactically, and/or diagnostically active substances.

**(C) The state of the prior art:**

The state of the art is very high in terms of therapeutic and diagnostically active substances. There is no evidence in the prior art that the instant composition would be usable as a preventative composition.

**D) The predictability or unpredictability of the art:**

There is no evidence in the prior art that the instant composition would be usable as a preventative composition

**(E) The relative skill of those in the art:** The level of ordinary skill in the art is high.

**(F) The amount of direction or guidance presented:** There is nothing in the specification that would indicate that the current invention prevents pain or inflammation from the medical conditions cited. No guidance for the preventative therapeutics is provided in the specification. The amount of direction or guidance is minimal or non-existent with regards to preventative drugs. Thus with respect to the instant composition, there is a substantial gap between treatment with therapeutics and prevention. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

**(G) The presence or absence of working examples:** The specification does not disclose any evidence that the specific substances lead to prevention.

**(H) The quantity of experimentation necessary:** In the instant case, there is a substantial gap between treatment and prevention in the case of preventative drugs. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

## **CONCLUSION**

Given the complete lack of direction in applicant's instant disclosure, the amount of experimentation required to realize the full scope of claims 73 is clearly undue.

***Information Disclosure Statement***

Information Disclosure statements filed on 21 July 2006 is acknowledged and has been reviewed.

***Claim Rejections- 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 73, 76-81-89,90-99, 107-115 rejected under 35 U.S.C. 103(a) as being unpatentable over Royer Garfield US 2003/0170307.

With regards to pending claim 73, US Royer Garfield 2003/170307 (hereafter the '307 publication) discloses a pharmaceutical composition comprising biodegradable hydrating ceramics (i.e. calcium sulfate), a expanding agent (sodium bicarbonate), a sorbed aqueous medium, and an bioactive agent such as anti-inflammatory agents ([0016], [0021], [0094]). The '307 publication teaches that the composition can be injected with subsequent formation of a solid in vivo ([0021]). The '307 publication teaches that the matrix has a porosity ([0037]). This reads on having a ruptured foam-like structure.

With regards to claim 81 which states in solid form has a ruptured structure obtained by disintegration into two or more parts, this is a product by process limitation and given little patentable weight for claims directed to the product.

The '307 publication teaches calcium sulfate in the form of a powder (Example 13, paragraph [0143]). The '307 publication teaches that the powder has a mean particle size of less than 50 microns.

The '307 publication teaches sodium bicarbonate which as evidenced by the specification is a gas-forming expandable agent (Example 15).

The '307 publication teaches the inclusion of polyethylene glycol (Example 13).

The '307 publication teaches having a shape of beads (paragraph [0072]).

The '307 publication teaches the matrix has a porosity and that the particle sizes measure in microns which reads on having a microporous structure.

With regards to the limitation that the active agent is homogenously dispersed, the prior art does not teach this, however it teaches that the active agent is dispersed and it would have been obvious to the skilled artisan to homogenously disperse the active agent to obtain an even distribution of the active agent.

With regards to the expandable agent is present at a concentration of at least about 0.1% w/w to about 10%, and the limitation wherein the sorbed aqueous medium is present in the composition at a concentration of about 30% w/w to about 60% w/w of the total composition; absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the concentrations of the expandable agent and sorbed aqueous medium.

With regards to the limitations of the %w/w of the active substance contained in the composition being released during specific time frames after implantation into a human; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed towards the composition is instantly claimed. Furthermore, these are functional limitations of the composition and it would be expected that the composition would exhibit these properties when in vivo.

With regards to the limitations claiming the percent of openings having a maximum width, absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having

ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the amount of openings and the width of them.

With regards to the surface area of the composition; absent evidence of criticality, since the values of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the surface area.

The '307 publication does not explicitly state the route of delivery is parenteral, however this is intended use and give little patentable weight. Furthermore, the composition of '307 publication, absent evidence to the contrary, would be capable for parenteral delivery.

Claims 74-75 rejected under 35 U.S.C. 103(a) as being unpatentable over US Royer Garfield 2003/170307 as applied to claims 73, 76-81-89,90-99, 107-115 above, and further in view of Stupak et al. US Patent 5, 162, 117.

The '307 publication does not teach the specific active agents flutamide, hydroxyl-flutamide, cyproteron, nilutamide, or bicalutamide, however, Stupak et al. US Patent 5, 162, 117 (hereafter the '117 patent) teaches controlled release of flutamide which can be combined with calcium sulfate (column 3, lines 35-44).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to substitute flutamide as the medicinal in the '307 publication. One would have been motivated to do so because the '307 publication teaches the inclusion of medicinal

such as antineoplastics and the '117 patent teaches that flutamide is a proven potent antiandrogen approved for the treatment of advanced prostate cancer (paragraph of line 20 column 1)

Claims 100-106 rejected under 35 U.S.C. 103(a) as being unpatentable over Royer Garfield 2003/170307 as applied to claims 73, 76-81-89,90-99, 107-115 above, and further in view of Ashton et al. US 2003/0158598.

The '307 publication does not teach a pore-sealing agent, however with regards to the composition including pore-sealing agents, Ashton et al. US 2003/0158598 (hereafter the '598 publication) teaches impregnating pores of a polymer matrix. The pores are impregnated with additives that are bioerodable and water-soluble. Contact with physiological fluid will dissolve the bio-erodible additives and enlarge the pores size of the polymer matrix increasing the surface area of the polymer matrix exposed to physiological fluid, thereby exposing the drug to the environment and accelerating release (paragraph [0127]). This will allow the drug to diffuse out of the polymer matrix more readily. These pore filling additives include PEG, hyaluronic acid. It would have been prima facie obvious to one of ordinary skill in the art to include pore-sealing agents. One would have been motivated to do so to obtain controlled release of an active agent. The '598 publication does not teach the specific pore-forming agents of pending claims 103, and 105, however the prior art recognizes the advantages of utilizing a pore-sealing agent and it would have been obvious to the skilled artisan to substitute one pore-sealing agent for another.

With regards to the concentration and amounts of pore-sealing agent; absent evidence of criticality, since the values of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust concentration of

the pore-sealing agent. Furthermore, MPEP 2144.05 states, ““where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization.”

***CORRESPONDENCE***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615